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ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/065,159	TKACZYK ET AL.	
	Examiner	Art Unit	
	Tran N. Nguyen	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

This communication is in response to the communication filed 09/21/2007. Pending claim(s): 1-40. Amended claim(s): 1, 14, 17, 30, 33.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 1-16 is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As per claim 1, Examiner cannot determine if "using" (line 2) refers to "a method" or "a clinical research entity".

For purposes of applying prior art, Examiner interprets this limitation to recite a method capable of providing a server system to a clinical research entity.

Claim 1 further recites "a server system coupled to a centralized database and at least one client system" (line 2-3). Examiner is unable to ascertain if Applicant intends to recite structural limitations within the scope of a method claim, or if Applicant intends to recite structural and functional limitations to the extent necessary to give meaning to the method steps.

For purposes of applying prior art, Examiner interprets this limitation to recite a method capable of providing a server coupled to a centralized database and at least one client system.

Claim 1 further recites "tracking" (line 11). Examiner cannot ascertain the meaning of this limitation when read in light of the specification.

For purposes of applying prior art, Examiner interprets this limitation to recite updating data.

Claim 1 further recites "information" (line 14). Based upon the broadest and most reasonable interpretation adopted by the Examiner, this step (line 14) recites that any information may be provided. As such, claim 1 is rejected because the provided information lacks a nexus with the remainder of the claim.

For purposes of applying prior art, Examiner interprets this limitation to recite CS information.

All claims dependent thereon, namely claims 2-13, fail to remedy these deficiencies, and are therefore rejected for at least the same rationale as applied to parent claim 1 above, and incorporated herein.

As per claims 14-16, these claims are rejected for at least the same rationale as applied to claims 1-13 above, and incorporated herein.

Additional clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim(s) 1-3, 6-9, 13-14, 16-19, 22-25, 29-30, 32-33, 36-38 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (6196970).

As per claim 1, Brown teaches a method (Abstract) capable of:

(a) collecting, analyzing, and aggregating (It is noted that collecting, analyzing, and aggregating are considered to be "managing") research data (It is noted that data is considered to be "information") during the source of research testing (Abstract), wherein the research testing is capable of being performed for a clinical trial (column 1 line 13 to column 3 line 10) or a clinical study (column 3 line 6);

(b) being used by a set of medical experts (Figure 1 label 121) and a set of research subjects (Figure 1 label 111) (It is noted that the set of medical experts and the set of research subjects, collectively, are considered to be "a clinical research study entity");

(c) providing a server-based system (Figure 1 label 100)) to the set of medical experts and the set of research subjects via a communications network (Figure 1 label 140), wherein the server-based system comprises a server device (Figure 1 label 130), a set of research subject devices (Figure 1 label 110), and a set of medical research expert devices (Figure 1 label 120) (It is noted that the set of research subject devices and the set of medical research expert devices are considered to be "at least one client system");

the method comprising:

(a) receiving, at the server device, information received from a research subject (It is noted that information received from a research subject is considered to be "CS information relating to at least one patient involved in a clinical study") (Figure 2a label 210), wherein:

(i) the information is received by the subject manipulating an input (It is noted that manipulating an input is considered to be "being entered") (Figure 2a label 207), thereby responding to a protocol (It is noted that a protocol is considered to be part of "a user selected template") (Figure 2a label 207-208) displayed by an output element (Figure 2a label 206), wherein the output element is part of the research subject device (Figure 1 label 112);

(ii) information concerning the type of data to be collected from the set of subjects (column 6 line 1-3) and the protocol (It is noted that information concerning the type of data to be collected and the protocol are considered to be "the user selected template") are sent to a database for storage (Figure 2a label 203-204), wherein:

(1) the subject views and responds to some portion of the protocol that was sent (It is noted that the information concerning the type of data to be collected and the protocol collectively determines what the subject views and respond to. It is further noted that Brown teaches that the database is capable of accumulating data even after the data is forwarded (column 7 line 27-29)) (column 6 line 19-20);

(2) the server device records the information concerning the type of data to be collected and protocol in the database (Figure 2a label 204);

(3) the server device records the modified protocol in the database (Figure 2b label 218);

(4) steps (2)-(3) are repeated (Figure 2b label 221), thereby creating a plurality of protocols stored in the database (It is noted that nowhere does Brown teach deleting, or otherwise expunging or purging, protocol from the database);

(5) the medical research expert either leave the protocol unchanged or modify the protocol as necessary (It is noted that a protocol is "selected" by the medical research expert for implementation) (column 7 line 3-5);

(5) the database is connected to a plurality of research subject devices (It is noted that the database connected to a plurality of research subject devices is considered to be "a centralized database") (Figure 1 label 110);

(6) each protocol includes receiving data from the subject according to a research testing goal (It is noted that a research testing goal is considered to be "specific clinical studies") (column 7 line 45-48);

(b) storing the information received from the subject in the database (Figure 2a label 210);

(c) repeatedly collecting information from the research subject (It is noted that repeatedly collecting information is considered to be "tracking CS information") (Figure 2b label 221);

(d) repeatedly collecting information from the research subject (It is noted that repeatedly collecting information is considered to be "updating the centralized database periodically", wherein information collected from the research subject is considered to be "newly received information") (Figure 2b label 221), wherein all information collected from the research subject resides in the database (column 7 line 27-29);

(e) providing the collected information to interested parties (It is noted that providing information to an interested party is considered to be "providing information in response to an inquiry") (column 6 line 52-54, column 7 line 29-30).

As per claim 2, Brown teaches aggregating, statistically analyzing, and sending from the server device to the medical research experts the information received from the research subject devices (It is noted that the aggregated and analyzed data is considered to be "at least one report summarizing information and findings") (column 6 line 45-51, Figure 2a label 211-212).

As per claim 3, Brown teaches aggregating, statistically analyzing, and sending from the server device to the medical research experts the information received from

the research subject devices (It is noted that the research subject is considered to be "at least one patient involved in a clinical study") (column 6 line 45-51, Figure 2a label 211-212).

As per claim 6, Brown teaches:

(a) determining and sending research information and protocol to the subject (Figure 2a label 205) (It is inherent that at least a portion of the protocol selected by the medical research expert is sent to the subject to provide the subject with instructions to operate the medical device, as discussed below);

(b) displaying the information received in (a) to the subject (column 6 line 18-23, Figure 2a label 206, Figure 1 label 112);

(c) responding to the protocol with data from the patient's medical device (column 4 line 9-12) (It is noted that data from the patient's medical device is considered to be "utilized medical equipment information").

Insofar as the remainders of the limitations of claim 6 are concerned, Brown need not teach these limitations in view of the limitation "at least one of".

As per claim 7, Brown teaches:

(a) responding to the protocol with data from the patient's medical device (column 4 line 9-12) (It is noted that data from the patient's medical device is considered to be "utilized medical equipment information"), aggregating and analyzing the data

(Figure 2a label 211) (It is noted that aggregating and analyzing data is considered to be "compiling a data report");

(b) sending the information received from the subjects to the various medical research experts (column 6 line 47-50, Figure 2a label 212) (It is noted that the various research experts are considered to be "a predesignated party").

As per claim 8, Brown teaches:

(a) evaluating the information by the protocol, and updating the information according to protocol logic as appropriate (column 6 line 55-60, Figure 2a label 213-214) (It is noted that a protocol residing on a server device is considered to be "at least one computer program").

As per claim 9, Brown discloses the method of claim 1, wherein presenting the protocol to subjects for response comprises:

(a) responding to the protocol with data from the patient's medical device (column 4 line 9-12) (It is noted that data from the patient's medical device is considered to be "utilized medical equipment information");

(b) sending the information received from the subjects to the various medical research experts (column 6 line 47-50, Figure 2a label 212).

Insofar as the remainders of the limitations of claim 9 are concerned, Brown need not teach these limitations in view of the limitation "at least one of".

As per claim 13, Brown teaches:

(a) connecting the research subject devices and the medical research expert devices to the server device via a communications network (Figure 1 label 140), wherein the network connects remote devices (Abstract) (It is noted that a network connecting remote devices is considered to be a "wide area network").

Insofar as the remainder of the limitations of claim 13 is concerned, Brown need not teach these limitations in view of the limitation "includes one of".

As per claim 14, Brown teaches a method (Abstract) capable of:

(a) collecting, analyzing, and aggregating (It is noted that collecting, analyzing, and aggregating are considered to be "managing") research data (It is noted that data is considered to be "information") during the source of research testing (Abstract), wherein the research testing is capable of being performed for a clinical trial (column 1 line 13 to column 3 line 10) or a clinical study (column 3 line 6);

(b) being used by a set of medical experts (Figure 1 label 121) and a set of research subjects (Figure 1 label 111) (It is noted that the set of medical experts and the set of research subjects, collectively, are considered to be "a clinical research study entity");

(c) providing a server-based system (Figure 1 label 100)) to the set of medical experts and the set of research subjects via a communications network (Figure 1 label 140), wherein the server-based system comprises a server device (Figure 1 label 130), a set of research subject devices (Figure 1 label 110), and a set of medical research

expert devices (Figure 1 label 120) (It is noted that the set of research subject devices and the set of medical research expert devices are considered to be "at least one client system");

(d) coupling a plurality of medical appliances to the system (column 5 label 11-13, Figure 1 label 114, column 6 line 27-36, Figure 2a label 207);

the method comprising:

(a) determining and sending research information and protocol to the subject (Figure 2a label 205) (It is inherent that at least a portion of the protocol selected by the medical research expert is sent to the subject to provide the subject with instructions to operate the medical device, as discussed below), wherein the protocol can include calling for data obtained by coupling the client device with another medical device (It is noted that calling for data obtained from a medical device is considered to be "protocols for operating the at least one medical device") (Abstract), wherein the plurality of medical appliances comprises a location sensing device and a digital video camera (column 6 line 35) (It is noted that a location sensing device and a digital video camera is considered to be "image data"), and wherein each protocol includes receiving data from the subject according to a research testing goal (It is noted that a research testing goal is considered to be "specific clinical studies") (column 7 line 45-48);

(b) coupling the medical appliance to the port of the subject device in response to the protocol (column 6 line 26-30) (It is noted that coupling the medical appliance in response to the protocol is considered to be "operating the at least one medical

device... based on the entered protocols"), wherein the digital video camera is capable of capturing images (column 6 line 35);

(c) receiving, at the server device, information received from a research subject (It is noted that information received from a research subject is considered to be "CS information relating to at least one patient involved in a clinical study") (Figure 2a label 210), wherein:

(i) the information is received by the subject manipulating an input (Figure 2a label 207), thereby responding to a protocol (Figure 2a label 207-208) displayed by an output element (Figure 2a label 206), wherein the output element is part of the research subject device (Figure 1 label 112);

(ii) information concerning the type of data to be collected from the set of subjects (column 6 line 1-3) and the protocol are sent to a database for storage (Figure 2a label 203-204), wherein:

(1) the subject views and responds to some portion of the protocol that was sent (column 6 line 19-20);

(2) the server device records the information concerning the type of data to be collected and protocol in the database (Figure 2a label 204);

(3) the server device records the modified protocol in the database (Figure 2b label 218);

(4) steps (2)-(3) are repeated (Figure 2b label 221), thereby creating a plurality of protocols stored in the database;

(5) the medical research expert either leave the protocol unchanged or modify the protocol as necessary (column 7 line 3-5);

(5) the database is connected to a plurality of research subject devices (It is noted that the database connected to a plurality of research subject devices is considered to be "a centralized database") (Figure 1 label 110);

(6) each protocol includes receiving data from the subject according to a research testing goal (It is noted that a research testing goal is considered to be "specific clinical studies") (column 7 line 45-48);

(d) storing the information received from the subject in the database (Figure 2a label 210);

(e) repeatedly collecting information from the research subject (Figure 2b label 221);

(f) repeatedly collecting information from the research subject (Figure 2b label 221), wherein all information collected from the research subject resides in the database (column 7 line 27-29);

(g) providing the collected information to interested parties (column 6 line 52-54, column 7 line 29-30);

(h) aggregating, statistically analyzing, and sending from the server device to the medical research experts the information received from the research subject devices (column 6 line 45-51, Figure 2a label 211-212).

As per the set of claim(s): 16, 17, 18, 19, 22, 23, 24, 25, 29, 30, 32, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 6, 1, 2, 3, 6, 7, 8, 9, 13, 14, 16, respectively, and incorporated herein.

As per claim 17, the output element of the research subject device (Figure 1) capable of displaying portions of the protocol (Figure 2a) is considered to be "a browser".

Claims 33, 36-38 recite a computer-readable medium containing software thereon, such that when the instructions contained therein are executed by the computer's processor, the functionality of the software is realized in the form of the method as recited in claims 1-3, 6-9.

It is noted that the scope of claims 33, 36-38 is substantially enveloped within the scope of claims 1-3, 6-9. See MPEP 2106.01(I). Therefore, claim 33, 36-38 are rejected for at least the same rationale as applied to claim 1-3, 6-9, and incorporated herein.

Specifically, the limitations "adding" and "deleting" data within a database is substantially enveloped by the limitation "updating".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-5, 15, 20-21, 31, 34-35 are rejected under 35 U.S.C. 102(b) as anticipated by Brown or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brown in view of Goldwasser (4737921).

As per claim 4, Brown teaches coupling a plurality of medical appliances to the system (column 5 label 11-13, Figure 1 label 114, column 6 line 27-36, Figure 2a label 207), wherein the plurality of medical appliances comprises a location sensing device and a digital video camera (column 6 line 35) (It is noted that a location sensing device and a digital video camera is considered to be "a computed tomography device").

Insofar as the limitations "a radiography device", "a positron emission tomography device", and "an ultrasound imaging device" are concerned, Brown need not teach these limitations in view of the limitation "at least one of".

Notwithstanding the above, Brown further teaches coupling a variety of medical appliances to the system (column 5 line 10-13) via a port (column 6 line 27-36).

Goldwasser teaches that using medical devices for medical research (column 2 line 48 to column 3 line 2), wherein the medical devices comprise computed tomography imaging technique (column 1 line 23-39), X-rays (column 1 line 17), PET (column 2 line 2), and ultrasound (column 2 line 14-16), is well known in the art.

All component parts are known. The only difference is the combination of "old elements into a single embodiment.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Goldwasser within the embodiment of Brown, since the operation of the medical devices is in no way dependent on the clinical study, and a standard medical device may be used with a clinical study system via a port to achieve the predictable result of sending additional data to the server (Brown; column 5 line 12-14).

As per claim 5, Brown teaches:

(a) determining and sending research information and protocol to the subject (Figure 2a label 205) (It is inherent that at least a portion of the protocol selected by the medical research expert is sent to the subject to provide the subject with instructions to operate the medical device, as discussed below), wherein the protocol can include calling for data obtained by coupling the client device with another medical device (It is noted that calling for data obtained from a medical device is considered to be "protocols for operating the at least one medical device") (Abstract);

(b) displaying the information received in (a) to the subject (column 6 line 18-23, Figure 2a label 206, Figure 1 label 112);

(c) coupling the medical appliance to the port of the subject device in response to the protocol (column 6 line 26-30) (It is noted that coupling the medical appliance in response to the protocol is considered to be "operating the at least one medical device based on the entered protocols");

(d) receiving by the server device information sent from the subject device (Figure 2a label 208-210), wherein the information sent comprises data from a digital video camera (column 6 line 35) (It is noted that data from a digital video camera is considered to be "diagnostic images").

Insofar as the limitation "x-rays" is concerned, Brown need not teach this limitation in view of the limitation "at least one of".

Notwithstanding the above, Goldwasser discloses that using medical devices for medical research (column 2 line 48 to column 3 line 2), wherein the medical devices comprise X-rays (column 1 line 17), is well known in the art.

All component parts are known. The only difference is the combination of "old elements into a single embodiment.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Goldwasser within the embodiment of Brown, since the operation of the medical devices is in no way dependent on the clinical study, and a standard medical device may be used with a clinical study system via a

port to achieve the predictable result of sending additional data to the server (Brown; column 5 line 12-14).

As per the set of claim(s): 15, 20, 21, 31, 34, 35, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 4, 4, 5, 5, 4, 5, respectively, and incorporated herein.

Claim(s) 10-11, 26-27, 39-40 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Rice (2002/0042723).

As per claim 10, Brown teaches:

(a) storing research information in the database, the information comprising information received from the subjects (column 7 line 29-30) (It is noted that it is inherent that the information comprises a list of patients).

Brown does not teach inquiring about a specific patient.

Rice teaches correlating FDA alerts with patient data (Abstract), wherein a list of patients is displayed (Figure 3).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Rice within the invention as described by the disclosure of Brown with the motivation of alerting doctors and nurses of patients

who are affected by the FDA alerts (Rice; paragraph 0007), and preventing patient deaths by failing to respond to incoming data in real time (column 2 line 45-67).

As per claim 11, Brown teaches:

(a) storing research information in the database, the information comprising information received from the subjects (column 7 line 29-30) (It is noted that it is inherent that the information comprises a list of patients).

Brown does not teach inquiring about a specific patient.

Rice teaches correlating FDA alerts with patient data (Abstract), wherein a list of patients is displayed (Figure 3).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Rice within the invention as described by the disclosure of Brown with the motivation of alerting doctors and nurses of patients who are affected by the FDA alerts (Rice; paragraph 0007), and preventing patient deaths by failing to respond to incoming data in real time (column 2 line 45-67).

Insofar as the remainder of the limitations of claim 11 is concerned, Brown and Rice need not teach these limitations in view of the limitation "at least one of".

As per the set of claim(s): 26, 27, 39, 40, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 10, 11, 10, 11, respectively, and incorporated herein.

Claim(s) 12, 28 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Applicant Admitted Prior Art (AAPA).

It is noted that the official notice taken in the previous Office Action is taken to be AAPA because Applicant failed to properly traverse Examiner's assertion.

As per claim 12, Brown teaches providing the information to interested parties (column 6 line 52-54, column 7 line 29-30), wherein the information is stored in the database (column 7 line 29-30).

Brown does not teach accessing, searching, or retrieving data from the database for display.

AAPA teaches:

(a) forming a query;

(b) transmitting the query to the a database;

(c) parsing of the query by the database;

(d) retrieving information stored in the database as indicated by the result of (c);

(e) returning the result of (d) for display;

is old and well established in the art of database.

All component parts are known. The only difference is the combination of "old elements into a single embodiment.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of AAPA within the embodiment of Brown, since the operation of processing database queries is in no way dependent on

the clinical study method, and a standard DBMS may be used with any clinical study system comprising a database to achieve the predictable result of obtaining the data contained therein.

As per the set of claim(s): 28, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 12, respectively, and incorporated herein.

Response to Arguments

Applicant's arguments filed 09/21/2007 have been fully considered but they are not persuasive.

As per claims 1, 17, 33, on page 19 Applicant argues Brown does not teach "selecting a template from a plurality of templates stored in a centralized database".

Brown teaches that:

(a) the server device records the information concerning the type of data to be collected and protocol in the database (Figure 2a label 204);

(b) the server device records the modified protocol in the database (Figure 2b label 218);

(c) steps (a)-(b) are repeated (Figure 2b label 221), thereby creating a plurality of protocols stored in the database (It is noted that nowhere does Brown teach deleting, or otherwise expunging or purging, protocol from the database);

(d) the medical research expert either leave the protocol unchanged or modify the protocol as necessary (It is noted that a protocol is "selected" by the medical research expert for implementation) (column 7 line 3-5).

According to the teachings of Brown, a medical research expert is presented with the choice to either modify the protocol or leave the protocol as-is. When steps (a)-(b) are repeated, the database stores therein a plurality of protocols as the results of the medical research expert modifying the protocol during each repetition of the loop.

Examiner submits that when the medical research expert leaves a protocol as-is, the medical research expert is in effect "selecting" to implement the instant protocol over the plurality of protocols implemented in previous loops.

On page 20 Applicant asserts "Fig. 1 of Brown shows a server device 130 containing the protocol 131 and the database 132 as *separate and distinct structures*" (emphasis in original).

Brown teaches recording the protocol 131 in the database 132 (column 6 line 9-11, Figure 2a label 204).

On page 20 Applicant further argues Brown does not teach "a plurality of templates".

Webster's II Dictionary, Second Edition defines "template" as "a gauge or pattern... used in making or copying something accurately".

Brown teaches that:

(a) information concerning the type of data to be collected from the set of subjects (column 6 line 1-3) and the protocol are sent to a database for storage (Figure 2a label 203-204);

(b) the subject views and responds to some portion of the protocol that was sent (column 6 line 19-20).

Examiner submits that the information concerning the type of data to be collected and the protocol collectively are considered to be "a template", wherein the system of Brown uses the information and the protocol, as specified by the medical research expert, in conjunction with software, to accurately extract information from the research subject.

On page 21 Applicant asserts "the meaning of a "template"... is focused on a device or interface having a set of fields allowing "a user to enter specific CS (clinical study) data 92 or to display specific CS data 92 for a user to view and analyze".

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a set of fields allowing "a user to enter specific CS (clinical study) data 92 or to display specific CS data 92 for a user to view and analyze") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Assuming *arguendo* this limitation flows inherently therefrom, Brown teaches displaying a portion of the protocol to the research subject to extract a response via an input (Figure 2a label 206-207). Brown further teaches that a protocol can include questions for the subject (Abstract).

On page 21 Applicant asserts "the information entered into the user template is used to gather protocols for operating medical devices".

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the information entered into the user template is used to gather protocols for operating medical devices) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Assuming *arguendo* this limitation flows inherently therefrom, Brown teaches sending the information extracted from the research subject to the medical research expert (Figure 2b label 215) and modifying or leaving the protocol as-is (Figure 2b label 216), wherein the protocol can include calling for data obtained by coupling the client device with another medical device (It is noted that calling for data obtained from a medical device is considered to be "protocols for operating medical devices") (Abstract).

The remainder of Applicant's arguments on page 21-24 merely rehashes the arguments addressed above, the responses to which are incorporated herein.

As per claims 12, 28, on page 24 Applicant traverses the Official Notice.

Examiner submits class 707, and particularly subclass 3-4, the definition of which states "subject matter directed to methods of searching for (i.e., querying) data stored as a database in a computer or digital data processing system, including sequential searching, primary and secondary index searching, and bit-map searching of inverted lists or topological maps" and "subject matter directed to methods for translating an external access to a database or files into internal access to the database or files, and translation of an external query format into an intermediate or internal query format".

Examiner submits that query processing for DBMS is so notoriously well known that class and subclasses have been dedicated to such subject matter.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Brown (20030229514, 20040019259, unpublished application 09/203,882) further teaches embodiments of the "protocol".

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from Examiner should be directed to Tran N. Nguyen (Ken) whose telephone number is (571) 270-1310. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:00 pm, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, Examiner's Supervisor, Joseph Thomas can be reached on (571) 272-6776.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TN
11/14/2007

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